# FOLIC ACID AND ALFALFA

## The FALL Study

**Background:**

There have been reports that alfalfa sprouts will lower total cholesterol and LDL levels in the blood. This has not been tested in a prospective, randomized or blinded trial.

**Methods and Results:**

45 patients, most with known coronary artery disease and many under treatment for hyperlipidemia were selected for the study. Patients were randomly assigned to either Group A placebo, Group B low dose alfalfa, and 230 mcg of folic acid, or Group C double dose alfalfa and folic acid.

The trial was 6 weeks and all patients were instructed to follow a low fat, low cholesterol diet, perform regular exercise in moderation, and to take the medication regularly. Group A (placebo)-one capsule per day, group B-two capsules per day, and group C-two capsules twice per day.

| | Group A | Group B | Group C |
|---|---|---|---|
| **LDL** | 5.9% decrease | 16.6% decrease | 8.6% decrease |
| **HDL** | 3.2% decrease | 11.2% increase | 1.5% increase |
| **C-reactive protein** | 33.6% increase | 24.4% decrease | 50.4% decrease |
| **Homocysteine** | 5.6% increase | 11.5% decrease | 6.3% decrease |
| **Triglycerides** | 2.4% decrease | 1.4% decrease | 15.0% decrease |

**Statement:**

Cardiovascular disease is the most common cause of death and disability in the United States. More people die from cardiovascular disease than all of the other causes of death combined. Cardiovascular disease has been the most common cause of death in the United States since 1900 with the exception of

the year 1918, during a flu outbreak. Multiple epidemiologic and clinical blinded prospective studies have indicated that lowering LDL levels will decrease the risk of cardiac events in primary prevention and will decrease recurrent cardiac events and decrease mortality in secondary prevention. The FDA has approved many drugs to be used in lipid lowering. Approximately 15 billions dollars per year is spent on lipid lowering medications. An equal amount of money is estimated to be spent on dietary and herbal supplements that do not require FDA approval and which are primarily directed toward lowering the risk of cardiovascular events. There are reports that alfalfa sprouts will lower serum cholesterol LDL levels and possibly raise HDL levels.

Prospective studies using diet as a means of controlling risk factors for cardiac events and decreasing cardiac events have been disappointing. The information regarding omega-3 fatty acids probably offers our best opportunity in this regard. The Adult Treatment Panel III has recommended lifestyle changes including exercise and dietary modification as a major means of lowering cardiovascular risk and future cardiac events.

Among a list of emerging "risk factors" are homocysteine levels and C-reactive protein. Elevated levels of homocysteine are positively correlated with risk for CHD. Folic acid and possibly B vitamins 6 and 12 have been documented to lower homocysteine levels.

C-reactive protein (CRP) is a marker for inflammation. Coronary artery disease is an inflammatory disease and there is now substantial evidence that persons with elevated high sensitivity C-reactive protein (hs-CRP) are at increased risk for future cardiac events. Inflammation within coronary plaques leads to plaque rupture and cardiac events. Statin drugs and a healthy lifestyle are known to reduce high sensitivity C-reactive protein. The Writing group of the 2002 workshop on inflammation markers and cardiovascular disease recommended measurement of hs-CRP in conjunction with other risk factors in people with increased risk of coronary artery disease. In many studies hs-CRP has been a better predictor of future cardiac events than LDL.

With this in mind, we undertook a study to determine the effects of alfalfa sprouts and folic acid on

known risk factors of coronary artery disease including total cholesterol, LDL, HDL, triglycerides, high sensitivity C-reactive protein, homocysteine levels, and apolipoprotein (b).

All patients were already under some from of treatment for hyperlipidemia. The patients were advised not to change their medication prior to enrollment to the study or during the trial. The study was first discussed with the patients and they were supplied capsules which either contained placebo, Group B 560 mg of alfalfa sprout powder and 230 mcg of folic acid, 2 capsules each day for a total of 1,120 mg alfalfa sprout powder and 460 mcg of folic acid or Group C, 2 capsules twice a day for a total of 2,240 mg of alfalfa sprout powder and 920 mcg of folic acid.

All patients underwent a history and physical exam prior to the start of the study and prior to blood samples being obtained. All patients received instruction in a low fat, low cholesterol diet, similar to the previously recommended Step 2, American Heart Association diet. All patients were instructed in exercise in moderation.

The majority of patients in this study were already following this type of lifestyle. Over 50% of the patients were already receiving statin drugs and many of the other patients were intolerant to statins because of myalgias or true rhabdomyolysis.

Many patients were already receiving folic acid.

**Results:**

1. All patients tolerated the medication well.
2. One patient in the placebo group stopped the medicine because she felt that the drug irritated her stomach.
3. One patient dropped out of Group C for personal reasons.
4. One patient in Group C who was taking 80 mg of an atorvastatin a day discontinued his atorvastatin during the study and therefore he had a marked increase in LDL level and his results were not included in the averages.

The results of the study were encouraging in that the LDL levels decreased in both treatment groups and more than in the placebo group. HDL also increased in both treatment groups and decreased in the placebo group. A surprising potential benefit of this treatment was the lowering of high sensitivity C-reactive protein levels. This has not been previously reported and the possible mechanism for this is not known, unless it is merely on the basis of lowering LDL levels. A similar lowering was not noted in the placebo group.

The results of the study are impressive since the average baseline LDL levels were only 133 and 151 in Groups B and C. The reason for a greater percentage reduction of LDL and raising HDL in Group B is not clear.

A combination of alfalfa sprout powder and folic acid appears to be a reasonable relatively inexpensive method for lowering one's risk for cardiac events. This should be tested in a larger, double blinded prospective trial to see if this not only lowers known cardiac risk factors but also lowers the number of cardiac events.

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